K040068

APR 1 6 2004

Ohmeda Medical BiliBlanket Plus High Output (67.5 μW/cm²/nm max) Phototherapy System (modified)

510(k) Summary

Submitter Information

Alberto F. Profumo, RAC (also contact person)
8880 Gorman Road
Laurel, MD 20723
Tel. 410-888-5204

Summary prepared on December 29, 2003

Device Name(s)

Classification Names:

- Neonatal Phototherapy Unit
- AC- powered Transilluminator

Common Names:

- Phototherapy Lamp
- Transilluminator

Proprietary Name:

- BiliBlanket Plus High Output Phototherapy System

Predicate Device Information

The BiliBlanket Plus High Output Phototherapy System is substantially equivalent to the following, legally marketed product:

Ohmeda – BiliBlanket Plus High Output (original) 510(k) No. K993712

Indications for Use

The BiliBlanket Plus High Output Phototherapy System provides light therapy for the treatment of hyperbilirubinemia, commonly know as neonatal jaundice, in the hospital or home setting. In addition, the device has an optional fiberoptic cable attachment for use in transillumination of the neonate.

Product Description

The BiliBlanket Plus High Output Phototherapy System has two modes of operation:

a) phototherapy, used for the treatment of hyperbilirubinemia; and

b) transillumination, used for a variety of medical procedures such as locating venipuncture sites and detecting pneumothoraces or hydrocephalus.

In the phototherapy mode, a fiberoptic cable and blanket are attached to the illuminator box. Phototherapeutic light, which is light in the blue region (425 – 475 nm), is transmitted from the illuminator to the blanket via the fiberoptic cable. The blanket is applied to the patient so as to maximize the patient contact with the blanket.

The second mode is transillumination. A fiberoptic cable is attached to the illuminator, and the visible light spectrum (white light) appears at the tip of this fiberoptic cable. This lighted cable is used for facilitating vascular stick or injections; it is also used for finding pneumothoraces. Transilluminators have been used, and are being used, in NICUs and nurseries all over the world. Their intended use and user familiarity are well established.

Description of Modification

Light output level increased from 18-45 ± 25% $\mu W/cm^2/nm$ to 21-50 +35% -25% $\mu W/cm^2/nm$

Performance Data

Since treatment of neonatal hyperbilirubinemia with phototherapy is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C -- Design Controls -- were satisfied.

Assessment of Technological Characteristics

The technological characteristics of the BiliBlanket Plus High Output Phototherapy System are similar to those of the predicate devices and do not raise new safety or effectiveness issues.

Sterilization Information

The BiliBlanket Plus High output Phototherapy System should not be sterilized. Cleaning and disinfecting instructions can be found in the Operation and Maintenance Manual. Disposable covers for the light emitting pad are available and instructions for their use are provided in the manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Alberto F. Profumo, R.A.C.
Director, Quality and Regulatory Systems
Ohmeda, Medical
8880 Gorman Road
Laurel, Maryland 20723

Re: K040068
Trade/Device Name: Biliblanket Plus High Output Phototherapy System
Regulation Number: 880.5400, 886.1945
Regulation Name: Neonatal Incubator, Transilluminator
Regulatory Class: II
Product Code: FMZ, HJM
Dated: January 12, 2004
Received: January 20, 2004

Dear Dr. Profumo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040068

510(k) Number (if known): K040068

Device Name: BiliBlanket Plus High Output Phototherapy System

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

William M. Burd for Chris Lem

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040068

Prescription Use ✓ **OR** **Over- The Counter Use** ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)